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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,889	07/16/2001	Hidenobu Sakamoto	210817US2	3675

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EXAMINER	
SHARON, AYAL I	

ART UNIT	PAPER NUMBER
2123	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,889	SAKAMOTO ET AL.	
	Examiner	Art Unit	
	Ayal I Sharon	2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/01,5/02,1/04,7/04*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Introduction

1. Claims 1-10 of U.S. Application 09/904,889 filed on 07/16/2001 are presented for examination. This application claims priority to Japanese Application 2001-14870, filed on 01/23/2001.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The prior art used for these rejections is as follows:

4. Yu, C., U.S. Patent No. 5,818,902. (Henceforth referred to as "**Yu**").

5. The claim rejections are hereby summarized for Applicant's convenience. The detailed rejections follow.

6. **Claims 1-3, 5-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu.**

7. In regards to Claim 1, Yu teaches the following limitations:

1. A radiation treatment system comprising:
simulation means (5,6,7) for executing radiation treatment simulation for dividing a radiation exposure region (3) and a peripheral region thereof to be irradiated with particle beams into a plurality of unit radiation exposure regions,

(Yu, especially: Fig.4 and associated text at col.11, lines 8-33)

In regards to "simulation means", Examiner interprets that Yu's controller corresponds to the claimed "simulation means for executing radiation treatment simulation." Moreover, Yu teaches the treatment of a "phantom box" in the "Example – Phase 1" (col.12, line 40 to col.12, line 58). Examiner finds this to be a "treatment simulation."

In regards to "particle beams", Yu teaches: "With intensity modulated arc therapy, most of the target will be in the beam during the delivery, maintaining a high efficiency in utilizing the photons generated in the X-ray target." (col.4, lines 2-5)

and then applying particle beams according to a shape of each divided unit radiation exposure region; and
(Yu, especially: col.3, line 5 to col.4, line 45)

Especially: "One of the key steps involved in creating optimized dose distributions using the present invention is directed to a method to convert the intensity distributions at all beam angles required by the treatment plan into multiple arcs." (col.4, lines 44-48)

radiation treatment planning means (4) for obtaining a radiation treatment condition for causing flatness, which is a degree of uniformly irradiating the radiation exposure region with a proper dose of particle beams, to be in a desired range,
(Yu, especially: col.3, line 5 to col.4, line 45)

Especially: "For intensity modulated arc therapy treatments, the leaf travel is continuous in the length direction of the leaves. The field aperture in the leaf width direction is collimated by the backup jaws and is, therefore, also continuous. Therefore, intensity modulated arc therapy can deliver higher dose conformity than tomotherapy."

and a dose of particle beams applied to the unit radiation exposure region of the peripheral region to be minimized, in the case where the simulation means executes the radiation treatment simulation,
(Yu, especially: col.3, line 5 to col.4, line 45)

Especially: "The present invention delivers high doses of ionizing radiation to the target tissues while minimizing dose[s] to the surrounding healthy tissues." (col.3, lines 15-17).

and then making a radiation treatment plan reflecting the radiation treatment condition.
(Yu, especially: Figs.5- 7, and associated text at col.12, line 40 to col. 13, line 38 "Example – Phase 1")

8. In regards to Claim 2, Yu teaches the following limitations:

2. The radiation treatment system according to claim 1, wherein the simulation means divides the radiation exposure region and the peripheral region thereof into unit radiation exposure regions of grid forms.
(Yu, especially: Figs. 1a and 11, and associated text at col.6, lines 29-45, and col.14, lines 22-35)

Yu also teaches that: "Finally, since the intensity modulation in tomotherapy relies on a set of veins to open or close the slit beam, the resolution of the beam intensities is the slit width by the vein width (commonly 1cm x 1cm). For intensity modulated arc therapy treatments, the resolution is the width of the vein in the vein width direction and continuous in the length direction of the veins." (col.12, lines 38)

Therefore, tomotherapy produces grid forms, and intensity modulated arc therapy produces belt-like radiation regions.

9. In regards to Claim 3, Yu teaches the following limitations:

3. The radiation treatment system according to claim 1, wherein the simulation means divides the radiation exposure region and the peripheral region thereof into belt-like unit radiation exposure regions.
(Yu, especially: Figs. 1a and 11, and associated text at col.6, lines 29-45, and col.14, lines 22-35)

Yu also teaches that: "Finally, since the intensity modulation in tomotherapy relies on a set of veins to open or close the slit beam, the resolution of the beam intensities is the slit width by the vein width (commonly 1cm x 1cm). For intensity modulated arc therapy treatments, the resolution is the width of the vein in the vein width direction and continuous in the length direction of the veins." (col.12, lines 38)

Therefore, tomotherapy produces grid forms, and intensity modulated arc therapy produces belt-like radiation regions.

10. In regards to Claim 5, Yu teaches the following limitations:

5. The radiation treatment system according to claim 1, wherein when the unit radiation exposure region is located in a boundary of the radiation exposure region, the radiation treatment planning means determines a degree of contribution made by a dose of particle beams applied to the unit radiation exposure region located in the boundary to the radiation exposure region, according to a dose of particle beams applied to the unit radiation exposure region of the peripheral region.
(Yu, especially: col.12, lines 58-65; Especially the isodose contours A, B, C, and D.)

11. In regards to Claim 6, Yu teaches the following limitations:

6. A radiation treatment method comprising:

a simulation step for dividing a radiation exposure region (3) and a peripheral region thereof to be irradiated with particle beams into a plurality of unit radiation exposure regions,
(Yu, especially: Fig.4 and associated text at col.11, lines 8-33)

In regards to "simulation means", Examiner interprets that Yu's controller corresponds to the claimed "simulation means for executing radiation treatment simulation." Moreover, Yu teaches the treatment of a "phantom box" in the "Example – Phase 1" (col.12, line 40 to col.12, line 58). Examiner finds this to be a "treatment simulation."

In regards to "particle beams", Yu teaches: "With intensity modulated arc therapy, most of the target will be in the beam during the delivery, maintaining a high efficiency in utilizing the photons generated in the X-ray target." (col.4, lines 2-5)

and then executing radiation treatment simulation according to a shape of each divided unit radiation exposure region;
(Yu, especially: col.3, line 5 to col.4, line 45)

Especially: "One of the key steps involved in creating optimized dose distributions using the present invention is directed to a method to convert the intensity distributions at all beam angles required by the treatment plan into multiple arcs." (col.4, lines 44-48)

a radiation treatment planning step for obtaining a radiation treatment condition for causing flatness, which is a degree of uniformly irradiating the radiation exposure region with a proper dose of particle beams, to be in a desired range,
(Yu, especially: col.3, line 5 to col.4, line 45)

Especially: "For intensity modulated arc therapy treatments, the leaf travel is continuous in the length direction of the leaves. The field aperture in the leaf width direction is collimated by the backup jaws and is, therefore, also continuous. Therefore, intensity modulated arc therapy can deliver higher dose conformity than tomotherapy."

and a dose of particle beams applied to the unit radiation exposure region of the peripheral region to be minimized, in the case where the simulation step is executed, and then making a radiation treatment plan reflecting the radiation treatment condition;
(Yu, especially: col.3, line 5 to col.4, line 45)

Especially: "The present invention delivers high doses of ionizing radiation to the target tissues while minimizing dose[s] to the surrounding healthy tissues." (col.3, lines 15-17).

and a radiation exposure step for applying particle beams to the radiation exposure region and the peripheral region thereof to be irradiated according to the radiation treatment plan made in the radiation treatment planning step.
(Yu, especially: Figs.5- 7, and associated text at col.12, line 40 to col. 13, line 38 "Example – Phase 1")

12. In regards to Claim 7, Yu teaches the following limitations:

7. The radiation treatment method according to claim 6, wherein in the simulation step, the radiation exposure region and the peripheral region thereof are divided into unit radiation exposure regions of grid forms.
(Yu, especially: Figs. 1a and 11, and associated text at col.6, lines 29-45, and col.14, lines 22-35)

Yu also teaches that: "Finally, since the intensity modulation in tomotherapy relies on a set of veins to open or close the slit beam, the resolution of the beam intensities is the slit width by the vein width (commonly 1cm x 1cm). For intensity modulated arc therapy treatments, the resolution is the width of the vein in the vein width direction and continuous in the length direction of the veins." (col.12, lines 38)

Therefore, tomotherapy produces grid forms, and intensity modulated arc therapy produces belt-like radiation regions.

13. In regards to Claim 8, Yu teaches the following limitations:

8. The radiation treatment method according to claim 6, wherein in the simulation step, the radiation exposure region and the peripheral region thereof are divided into belt-like unit radiation exposure regions.
(Yu, especially: Figs. 1a and 11, and associated text at col.6, lines 29-45, and col.14, lines 22-35)

Yu also teaches that: "Finally, since the intensity modulation in tomotherapy relies on a set of veins to open or close the slit beam, the resolution of the beam intensities is the slit width by the vein width (commonly 1cm x 1cm). For intensity modulated arc therapy treatments, the resolution is the width of the vein in the vein width direction and continuous in the length direction of the veins." (col.12, lines 38)

Therefore, tomotherapy produces grid forms, and intensity modulated arc therapy produces belt-like radiation regions.

14. In regards to Claim 10, Yu teaches the following limitations:

10. The radiation treatment method according to claim 6, wherein in the radiation treatment planning step, when the unit radiation exposure region is located in a boundary of the radiation exposure region, determination is made as to a degree of contribution made by a dose of particle

beams applied to the unit radiation exposure region located in the boundary to the radiation exposure region, according to a dose of particle beams applied to the unit radiation exposure region of the peripheral region.
(Yu, especially: col.12, lines 58-65; Especially the isodose contours A, B, C, and D.)

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The prior art used for these rejections is as follows:

17. Yu, C., U.S. Patent No. 5,818,902. (Henceforth referred to as "**Yu**").

18. Pugachev et al., U.S. PG-PUB No. 2002/0051513 A1. Provisional Application filed 9/25/2000. (Henceforth referred to as "**Pugachev**").

19. The claim rejections are hereby summarized for Applicant's convenience. The detailed rejections follow.

20. Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu in view of Pugachev.

21. In regards to Claim 4, Yu does not expressly teach the following limitations:

4. The radiation treatment system according to claim 1, wherein the simulation means divides the radiation exposure region and the peripheral region thereof into concentric circular unit radiation exposure regions.

Pugachev, on the other hand, teaches gantry angles Θ_1 and Θ_2, which have a range of 0° to 360°. (See Fig.1 and associated text at para.42.) It is

inherent that a gantry angle of 180° or more would generate concentric circular unit radiation exposure regions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Yu with those of Pugachev, because Pugachev's invention "... provide[s] a method for scoring and selecting gantry angles in a manner which is simple and easy to implement in the clinical environment." (para.14).

22. In regards to Claim 9, Yu does not expressly teach the following limitations:

9. The radiation treatment method according to claim 6, wherein in the simulation step, the radiation exposure region and the peripheral region thereof are divided into concentric circular unit radiation exposure regions.

Pugachev, on the other hand, teaches gantry angles Θ_1 and Θ_2, which have a range of 0° to 360°. (See Fig.1 and associated text at para.42.) It is inherent that a gantry angle of 180° or more would generate concentric circular unit radiation exposure regions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Yu with those of Pugachev, because Pugachev's invention "... provide[s] a method for scoring and selecting gantry angles in a manner which is simple and easy to implement in the clinical environment." (para.14).

Correspondence Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ayal I. Sharon whose telephone number is (571) 272-3714. The examiner can normally be reached on Monday through Thursday, and the first Friday of a biweek, 8:30 am – 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Teska can be reached at (571) 272-3716.

Any response to this office action should be faxed to (703) 872-9306, or mailed to:

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or hand carried to:

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center 2100 Receptionist, whose telephone number is (571) 272-2100.

Ayal I. Sharon

Art Unit 2123

March 31, 2005